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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/847,134	05/02/2001	Timothy J. Hoffman	0994.00131	8994

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EXAMINER

JONES, DAMERON L

ART UNIT

PAPER NUMBER

1616

DATE MAILED: 11/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	09/847,134	HOFFMAN ET AL.
	<b>Examiner</b>	<b>Art Unit</b>
	D. L. Jones	1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on \_\_\_\_\_.  
 2a) This action is **FINAL**.      2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 3-13,15-36 and 38-61 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_ is/are allowed.  
 6) Claim(s) 3-13,15-36 and 38-61 is/are rejected.  
 7) Claim(s) \_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. _____. 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____. 6) <input type="checkbox"/> Other: _____.	

## COMMENTS/NOTES

1. The following action is deemed necessary in order to clarify the instant invention and ensure consistency between the language of the specification and claims.

## ACKNOWLEDGMENTS

2. The Examiner acknowledges the amendment filed 7/23/04 wherein claims 1, 2, 14, and 37 are canceled and claims 4, 6, 11, 17, 19, 33, 41, 42, 49, 50, 58, and 61 are amended.

**Note:** Claims 3-13, 15-36, and 38-61 are pending.

## NEW GROUNDS OF REJECTION

### **112 Rejections**

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 3-13, 15-36, and 38-61 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims as written are ambiguous because one cannot readily ascertain what is being claimed. In particular, claims 3, 15, 38, 47, 53, and 54 are directed to a compound has the structure X-Y-B wherein X is a metal chelating receptor agonist; Y is a spacer group or covalent bond selected from the group consisting of at least one amino acid residue, a hydrocarbon chain, or combinations thereof; and the variable B is

defined as a gastrin releasing peptide receptor agonist which *includes* a bombesin agonist binding moiety. However, on page 7 (lines 1-5) of the specification, the general formula X-Y-B is disclosed and B is defined as a bombesin agonist binding moiety, not a gastrin releasing peptide receptor agonist which includes a bombesin agonist binding moiety. Furthermore, it is noted that in some of the dependent claims (i.e., claims 5, 18, and 34), the variable B has been identified as a bombesin moiety, not a gastrin releasing peptide receptor agonist that includes a bombesin agonist binding moiety. Also, it is noted that the preamble of some of the claims (i.e., claims 3 and 38) discloses that the gastrin releasing peptide receptor agonist includes a bombesin agonist binding moiety. Applicant is respectfully requested to clarify the claims to be consistent with the disclosure of the specification.

### **103 Rejections**

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 3-7, 12, 15-20, 34, 38-43, 46-51, and 53-60 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Albert et al** (US Patent No. 5,686,410).

**Albert et al** disclose a composition for diagnostic and therapeutic purposes comprising a biologically active peptide (i.e., a gastrin releasing peptide or bombesin,

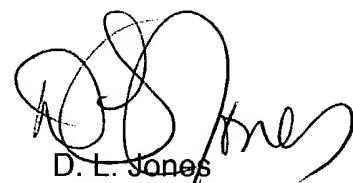
see entire document, especially, column 2, lines 24 and 25) in combination with at least one chelating group linked directed or indirectly to the peptide using spacer or linking groups (column 7, lines 47-59; column 11, lines 25-58; column 14, lines 4-10). Possible chelating groups include EDTA, DTPA, DOTA, TETA, HBED (column 3, lines 47-68). Possible detectable metals which may be conjugated to the chelating moiety include heavy elements, rare earth ions, paramagnetic ions, fluorescent ions, and radionuclides (columns 12, lines 56-68; column 13, lines 1-29). While Albert et al disclose bombesin, the reference does not specifically state that it is a bombesin agonist.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to generate a compound a bombesin agonist, spacer group, and metal chelating group because the cited prior art discloses polypeptide compositions comprising a chelating group attached directly or indirectly (with a spacer/linker) to the peptide wherein the peptide may be bombesin or a gastrin releasing peptide. Thus, both Applicant and Albert et al disclose compositions encompassed with Applicant's formula X-Y-B wherein X is a metal chelating group; Y is a spacer or covalent bond selected from an amino acid residue, a hydrocarbon chain, or combinations thereof; and the variable B is a gastrin/bombesin. Furthermore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use a bombesin agonist because the reference discloses bombesin and bombesin antagonists, thus a skilled practitioner in the art would recognize that the group (genus) 'bombesin' would encompass bombesin agonist.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. L. Jones whose telephone number is (571) 272-0617. The examiner can normally be reached on Mon.-Fri., 6:45 a.m. - 3:15 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (571) 272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



D. L. Jones  
Primary Examiner  
Art Unit 1616

November 12, 2004